SCIENTIFIC Conference

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Europe

IABS

International Alliance for Biological Standardization

Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

May 14 & 15, 2025

BRUSSELS, BELGIUM

www.iabs.org

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About the Conference

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Platforming technologies are now widespread in biotechnology for both human and veterinary products. They have demonstrated their effectiveness and serve as powerful tools throughout cell line development, upstream and downstream operations, formulation development, and analytical testing. Platforms utilize prior knowledge and shared industry experiences to speed up the development of innovative medicines. Additionally, contract development and manufacturing companies (CDMOs) heavily utilize platforms to work across products to help clients bring innovative new medicines to the clinic.

However, there are no universal standards on how to create, justify and support platforms across the pharmaceutical industry and disciplines. Including platform information and the specific non-product level of detail in dossiers is key for regulatory agencies to evaluate a platform's robustness and applicability using tools such as a risk-based assessments. Rationale and justification on how prior knowledge and platform data is suitable for the intended product is essential in a review.

This Workshop will explore the use of platform approaches and technologies in development and registration. It will include case studies demonstrating how prior knowledge for a platform is applied across products. The objective is to help developers and manufacturers work with health authorities to align expectations from Phase 1 development through commercialization. Additional topics covered will include creating, verifying, and maintaining platforms, their lifecycle, using them in regulatory submissions, and transitioning from first-in-clinic trials to commercial approval.

Scientific and Organizing Committee

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Scientific Committee

Shawn Novick - IABS Chair
Tura Camilli - Amgen
Jean-François Dierick - GSK
Marcel Hoefnagel - MEB
Christopher Carl Frye - Eli Lilly & Co
Caroline Leveder - Sanofi
Mourad Mellal - Catalent
Nadine Ritter - Global Biotech Experts
Marc Verhagen - Sanofi

Organizing Committee

Shawn Novick - IABS Chair
Madinina Cox - Events Manager - IABS/MC'Com, France

Scientific Program

Wednesday, May 14, 2025

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8:30 - 8:45 — Official Welcome from IABS
Shawn Novick, IABS Vice-President

Session I - Laying the Foundation: Platform Definition, Creation and Lifecycle (or Challenges and Opportunities with Platforms for Biologics?)

Moderators: Mourad Mellal, Catalent & Jean-François Dierick, GSK

8:45 - 9:15 — Platforms in Biotechnology Development and Manufacturing: Laying the framework
Jason Starkey, Pfizer

9:15 - 9:45 — Summary of the Quality Innovation Group Listen and Learn Focus Group (LLFG) meeting on Platforms (November 2024)
Marcel Hoefnagel, MEB

9:45 - 10:15 — Industry Perspectives: Sponsors Platform Analytical Procedures and Opportunities From ICH Q2 Q14
Jean-François Dierick, GSK

10:15 - 11:00 — *Coffee & Tea Break*

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11:00 - 11:30 Standardized Platform Process With In-Line Cell Lysis Purifies Plasmid DNA Using A Single Chromatographic Step For Cell And Gene Therapy
Sebastien Gillet, Catalent

11:30 - 12:30 Panel Discussion with Veronika Jekerle, EMA

12:30 - 1:45 *Lunch Break*
POSTER SESSION

Session II – The Use of Platform Capabilities in Late-Stage Development and Commercial Applications

Moderator: Christopher Carl Frye, Eli Lilly & Co

1:45 - 2:15 Analytical Platform Case Study: Is The Charge Assay Suitable As Platform Procedure?
Nermin Buza, Novartis

2:15 - 2:45 The Role of Platform Host Cell Protein ELISAs in Biopharmaceutical Quality Control
Florian Semmelmann, Roche

Scientific Program

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2:45 - 3:15	Leveraging Prior Knowledge for Process Parameter Classification in mAb Protein A Chromatography **Yinying Tao** - Lilly
3:15 - 3:45	*Coffee & Tea Break*
3:45 - 4:15	Leveraging Prior Knowledge and Platform Technologies to Streamline Biologics Drug Product Development **Sy Gebrekidan**, Johnson & Johnson
4:15 - 4:30	Capturing the Essence of a Purification Step: Data-Driven Simplification of a Protein Purification Platform **Yannick Van Haelst**, Sanofi
4:30 - 4:45	*Mini Break*
4:45 - 5:30	Panel Discussion
5:30	End of Day 1

Scientific Program

Thursday, May 15, 2025

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8:30 - 8:45 Official Welcome from IABS
Shawn Novick, IABS Vice-President

Session III - Platforms Go Commercial: Lifecycle Management of Approved Platforms - prior knowledge vs platform filing

Moderator: Marc Verhagen, Sanofi

8:45 - 9:15 The Journey of Compendial General Analytical Procedures: From Establishment to Lifecycle Management
Mihaela Buda, EDQM

9:15 - 9:45 Commercial Submission Considerations for Platform Analytical Procedures
Karen Rule, Pfizer

9:45 - 10:15 Platform Lifecycle Management of Commercial Products
Kowid Ho, Roche

10:15 - 10:45 *Coffee & Tea Break*

Scientific Program

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10:45 - 11:15 The Use Of Platform Technologies In Regulatory Applications For Veterinary Vaccines In The European Union – Perspective From The Pharmaceutical Industry
Frederic Descamps, Zoetis

11:15 - 12:15 Panel Discussion

12:15 - 1:15 *Lunch Break*
POSTER SESSION

Break-Out Working Sessions: Early Phase/Commercial Platforms

Moderators: Nadine Ritter, Global Biotech Experts, Shawn Novick, IABS, Jean-François Dierick, GSK & Caroline Leveder, Sanofi, Ruby Casareno

1:15 - 2:30 4 Break-Out Working Sessions:
Early Phase Process/Analytical
Commercial Process/Analytical

2:30 - 3:00 Feedback

3:00 - 3:30 *Afternoon break*

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Session IV – Remaining Hurdles: Sponsor Master Files? CDMO Master Files? Global Acceptance of Platforms?

Moderator: Nadine Ritter, Global Biotech Experts

3:30 - 4:00	Thoughts from a former regulator on platform technologies, platform technology designation, and the use of contract manufacturing/testing organizations for biotechnology products **Marjorie Shapiro**, FDA-CDER retired
4:00 - 4:30	Perspective, Regulatory, or other presentation style without primary data: Industry Proposal – EFPIA/CEPI White paper platform MFs **Mihai Bilanin**, GSK
4:30 - 5:00	Leveraging platform approaches in regulatory filings
5:00 - 5:45	Panel discussion
5:45	End of meeting

Upcoming IABS Conferences and Workshops

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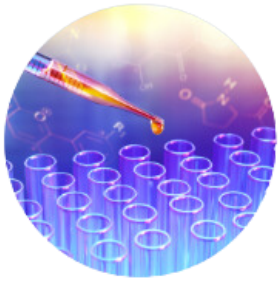
Workshop on Global Harmonization of Specification: Implementing A Patient-Centric Control Strategy

Tokyo, Japan
June 23-25, 2025

11th Annual Statistics Workshop Big Tent Statistics – Conveying The Importance Of Statistical Contributions

Rockville, MD, USA
October 22-24, 2025



AFSA – IABS Conference about Animal testing replacement for vaccines: A One Health View: global outlook and future strategy

Bangkok, Thailand
December 2-4, 2025

Advances in Analytical Technologies for Biopharmaceutical Products

Rockville, MD, USA
March, 2026

Biosketch

Mihai Bilanin, PhD

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GSK Biologicals S.A.

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Mihai Bilanin has spent over 23 years in the pharmaceutical industry, with the last 20 years in Global Regulatory Affairs in Canada and Europe. He has managed and led worldwide regulatory strategy and projects in development, registration and life-cycle management (various degrees of complexity), in pharma, and for the last 13 years, in vaccines in both CMC Excellence and Therapeutic Group Vaccines' regulatory strategy functions. Latterly Mihai has focused on global regulatory strategies related to new vaccines' developments, in addition to leading an EFPIA/VE industry team of experts on developing and contributing to a world-leading' platform technology regulatory framework in Europe. He currently works for GSK Biopharmaceuticals (Vaccines) and is based in Belgium.

Abstract

Mihai Bilanin

Perspective, Regulatory, or other presentation style without primary data: Industry Proposal – EFPIA/CEPI White paper platform MFs

Background OR Introduction:

Enabling innovation in manufacturing, via a world leading regulatory framework, is a critical requirement for Europe to maintain its competitiveness and leading position as a supplier of medicines to the world.

Challenges OR Issues:

Many manufacturing processes and control strategies use similar or identical platforms to deliver quality medicines. As a result, during the registration of a new Marketing Authorisation Application (MAA) or submission of a Clinical Trial Application (CTA) for human medicines and their respective lifecycle (LC) submissions, applicants often reproduce the same or similar information in regulatory dossiers which are applicable equally to multiple products, even if this information has already been approved by a competent authority, leading to redundant reassessments of the same information in multiple applications. Current uses of MF (ASMF, PMF and VAMF) are limited in scope and do not support efficient authoring, submission or review of MAAs or CTAs when materials, components or platform technologies are used that can apply to multiple products.

Proposed Approach, Approach Being Taken, Proposed Solutions, OR Relevant Guidance:

EFPIA/VE has developed an industry position related to key guiding principles that can facilitate and enable the deployment of platforms and the use of prior-knowledge through the development of a world-leading regulatory tool (i.e., Platform Technology Master Files across modalities, see * Expanding Master Files for human medicinal products in the EU/EEA)

This position paper focuses on the significant need for an extended MF concept that would be widely applicable across therapeutic modalities, materials and components used in the manufacture of finished drug products. It would apply across the development and lifecycle of the materials and could also support the provision of process & analytical prior knowledge.

Conclusions:

The significance of these "platform technology master file" concepts to patients and the modernization of manufacturing cannot be overstated for a rapid development, scale up and supply and for enabling innovation in manufacturing and development of new, complex active substances, finished products and devices.

Biosketch

Mihaela Buda

Head of Section Biological Standardisation Programme

EDQM/Council of Europe

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Mihaela is a chemist with a PhD in pharmaceutical chemistry from the Ruprecht-Karls University of Heidelberg, Germany. After completing post-doctoral research at the University of Heidelberg's Institute for Pharmacy and Molecular Biotechnology, she joined the Institute for Reference Materials and Measurement at the Joint Research Centre (JRC) of the European Commission, where she focused on developing and certifying reference materials for quality control in bioanalysis. In 2013, she became a Scientific Programme Manager at the European Directorate for the Quality of Medicines & HealthCare (EDQM), contributing to the development of European Pharmacopoeia documentary standards for biotherapeutics (including monoclonal antibodies), mRNA vaccines, and plasma-derived medicinal products. She was actively involved in the early work of the Analytical Quality by Design Working Party, helping shape its strategic direction. Since 1 January 2025, she has taken up the role of Head of Section for the Biological Standardisation Programme at the EDQM.

Abstract

Mihaela Buda

Title: The Journey of Compendial General Analytical Procedures: From Establishment to Lifecycle Management

European Pharmacopoeia (Ph. Eur.) standards are a key component of the regulatory framework. They rely on specifications for products approved in the Ph. Eur. member states, and are established and maintained through a rigorous process, based on robust data and sound scientific principles. Compendial general analytical procedures are designed for broad applicability across multiple (types of) products, with specific steps required to demonstrate suitability for a specific product. This presentation will highlight key concepts underlying these analytical procedures and their lifecycle, from establishment to implementation, including also elements such validation, revalidation of technical modifications to existing procedures, and comparability of alternative analytical procedures. Drawing on recent examples from the standardisation of methodologies for monoclonal antibodies' analysis, the presentation will illustrate how the Ph. Eur. ensures that these procedures remain scientifically robust, offering insights to broader analytical procedure lifecycle strategies to enable flexibility and innovation.

Abstract

Nermin Buza

Analytical Platform Case Study: Is The Charge Assay Suitable As Platform Procedure

Charge separation analytical procedures are commonly used for biological product characterization and quality control. To enable a fast an easy applicability of this technology for monoclonal antibodies and similar products entering our development pipeline, we used AQbD tools such as risk assessment and DoE to define critical method parameter and ranges for robust charge variant quantification of several molecules. For the establishment of the platform procedure, 12 different IgGs were analyzed using 3 different columns under variations of several method parameters. The method parameter design space was later fully validated at the min/max acceptable ranges using 3 IgGs. The predefined parameter ranges and understood interactions of method inputs to method outputs relevant to achieve the desired method performance enable easy parameter set-point adaptions to achieve a reliable charge variant resolution for the new molecules. Challenges however remain for the registration of the platform procedure adaptation, transfer and submission strategy of a potentially abbreviated validation, when the platform procedure is applied for new IgGs that enter the market application phase.

Biosketch

Ruby Casareno, PhD

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Experienced CMC executive with 25 years of building and leading cross-functional teams in the biotechnology industry. Skilled in biologics product development, including cell line, cell culture, purification, analytical and formulations development, quality control, scale up, tech transfer, process characterization and validation, selecting/partnering with contract manufacturers, CMC project management, supply chain and logistics. Contributed to 3 commercial (Adcetris, Andexanet alfa, Natrecor) and 24+ clinical programs. Ruby Casareno, PhD, served as SVP, Head of CMC and Technical Operations at Allakos Inc for 5 years taking the lead program from Ph2 to completion of BLA-enabling activities, and phase-appropriate buildup of the CMC team. Prior to that, Ruby supported the approval of Andexa at Portola as Director of Outsourced Manufacturing and MSAT and Adcetris at Seattle Genetics. In addition, Ruby supported 9 clinical programs as Director of Process Devt and Manufacturing at OncoMed. Ruby has been an independent Biologics CMC consultant since 2022, helping clients with their drug development efforts, evaluating/selecting CDMOs, providing Module 3 writing/editing services and performing due diligence. Ruby received her PhD from The Ohio State University and held Postdoctoral Fellowships at Washington University School of Medicine and at UCSF.

Biosketch

Frédéric Descamps

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Frédéric Descamps graduated as Veterinarian from the Faculty of Liège, Belgium, and obtained his PhD on the pathogenesis and immunology of Microsporum canis in cats in the same faculty. He has been working in the field of Veterinary Regulatory Affairs since 2003, first in the public sector where he has been acting as Senior Assessor at the Belgian Medicine Agency and as Belgian alternate CVMP member at the European Medicines Agency. Then he moved to the Veterinary pharmaceutical Industry in 2011. He is now Senior Director of Regulatory Affairs at Zoetis. He is also Chair of the Biological Working Party of AnimalHealthEurope. His primary responsibility is to develop new biological products (vaccines in particular) and maintain existing products on the market.

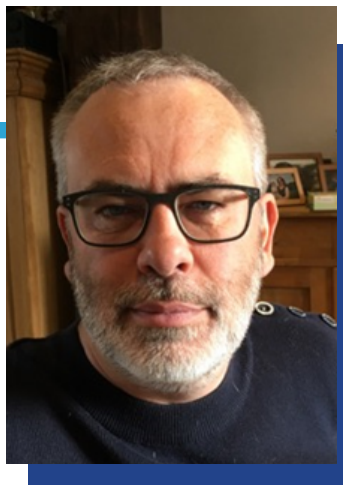
Abstract

Frédéric Descamps

Use of platform technologies in regulatory applications for veterinary vaccines in the European Union – Perspective from the pharmaceutical industry.

This presentation will provide the perspective (benefits and challenges) from the veterinary pharmaceutical industry on 3 types of platform technologies that can be used in regulatory applications for veterinary vaccines in the European Union: the vaccine platform technology master file [vPTMF], the vaccine antigen master file [VAMF] and the multi-strain [MS] dossier. Since the actual implementation of the Regulation 2019/6 that introduced or modified those concepts and came into force in 2022, the veterinary industry has quickly gained experience with those, since several vPTMFs and VAMFs have already been certified by the EMA, and several MS dossiers have been approved. A vPTMF is a file containing comprehensive data on a vaccine platform's manufacturing, quality control, stability, safety, and efficacy. Once a vPTMF is certified, the data already approved in the vPTMF do not need to be re-assessed for subsequent products using the same vPTMF. A VAMF is a comprehensive dossier that contains all the detailed quality-related information about a specific antigen used in vaccine production. Once a VAMF is certified and the corresponding antigen is used in a new vaccine, the data already certified do not need to be re-assessed by the regulatory authorities. A MS dossier means a single dossier containing the relevant data for a unique and thorough scientific assessment of the different options of strains/combinations of strains permitting the authorisation of inactivated vaccines against antigenically variable viruses or bacteria for which rapid or frequent change in the composition of vaccine formulations is needed to ensure efficacy with regard to the epidemiological situation in the field. A MS dossier covers a number of different strains of a single virus species, bacteria genus or vector produced according to the seed lot system. The formulation of the final product includes a specification for the maximum antigen content per strain and the maximum number of strains in accordance with the safety data submitted with the application.

Biosketch



Jean-François Dierick

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Jean-Francois Dierick holds a PhD in Biology from the University of Namur (Be), in the field of proteomics of cellular ageing and a post-doc in proteomics from the University of Brussels (Be). Jean-Francois Dierick entered the pharmaceutical world working for SGS, where he was leading the Biology Department (Biotechnology, Biochemistry, Cell Biology, Molecular Biology, Microbiology, Toxicology) from the site of Bierges (Be). In 2008, he joined GSK Vaccines where he has occupied several positions in the field of the analytics of biological products; both in the development and the commercial spaces. Today, he is working in GSK as Strategic Analytical Validation and Lifecycle Lead / Vx Analytical R&D, leading the transformation and/or implementation of analytical lifecycle process (ex: ICH Q2 and Q14, platformization, …).

Abstract

Jean-François Dierick

Industry Perspectives: Sponsors Platform Analytical Procedures and Opportunities From ICH Q2 Q14

The new version of ICH Q2 (R2) "Validation of Analytical Procedure" and the new ICH Q14 "Analytical Procedure Development" are addressing topics in the mood of time (Real-Time-Release, multivariate models, …), these two guidelines bring the concepts of Analytical Quality by Design through the description of an "enhanced approach". The two texts also address the topic of platform analytical procedures but not in great details, and probably to an extent that does not allow the immediate realization of the game changing potential of the application of AQbD concepts to platform analytical procedures development, validation and lifecycle.

The objective of the presentation is to share a vision where the concepts from the enhanced approach (ATP, risk management, knowledge management, validation, assay control strategy, change management) can accelerate the availability of more robust validated platform analytical procedures, can facilitate the extension of usage to new products, and contribute to the reduction of product development lead time.
The positioning will be knowingly progressive in order to stretch towards the most ambitious vision and to envisage together the long-range benefits that are possible but not promised and, in any case, depend on how we will implement ICH Q2 and Q14.

Biosketch

Christopher Carl Frye, Dr

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Dr. Christopher Frye is currently Vice President and Senior Research Fellow within Eli Lilly & Company's Bioprocess R&D (BR&D) organization. Chris completed his undergraduate studies in Microbiology and received his doctorate in Molecular Biology and Biochemistry from Indiana University. He has been a researcher at Lilly for nearly 35 years, all of which has been spent within BR&D. During his tenure at Lilly, Chris has been involved in developing drug substance and drug product manufacturing processes, primarily supporting the clinical development and commercialization of therapeutic proteins and a wide range of bioconjugates. He has leveraged both mammalian and microbial expression systems to develop effective, efficient manufacturing "platforms" supporting the Lilly's diverse large molecule portfolio. A focus of Chris' efforts has been centered on continual process improvement and the implementation of innovative technologies to ensure capability in meeting the needs of an evolving portfolio and accelerating delivery of medicines to patients.

Biosketch

Sy Gebrekidan, PharmD, Ph.D.

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Sy Gebrekidan, PharmD. PhD. is Senior Director of Biologics Drug Product Development & Delivery at Johnson & Johnson Innovative Medicine, R&D. He has over 25 years of experience in formulation, process development and commercialization of drug products having previously worked at Merck, GSK, and Pfizer. Dr. Gebrekidan serves on the Leadership Group of the Biologics CMC of the IQ consortium, Board of Directors of the subcutaneous consortium, on the editorial Board of the Journal of Drug Development and Industrial Pharmacy and as Scientific Advisor to the Editors of the Journal of Pharmaceutical Sciences. Dr. Gebrekidan has a PhD in pharmaceutical Sciences from the University of Kentucky (USA), PharmD in Pharmacy from Creighton University (USA) and Bachelor`s in Chemistry from Berea College, USA.

Abstract

Sy Gebrekidan

Leveraging Prior Knowledge and Platform Technologies to Streamline Biologics Drug Product Development

Background OR Introduction:

Biologic therapeutics have been transformational in the treatment of diseases and will continue to grow in importance over the next decade. The promise of these therapeutics has necessitated the need to accelerate their development and commercialization.

Challenges:

However, due to the inherent complexity of Biologics, acceleration can be challenging. Additionally, the amount of material available for development is frequently limited. Therefore, it is critical to employ efficient development strategies and processes that enable successful development.

Proposed Approach, Approach Being Taken, Proposed Solutions, OR Relevant Guidance:

Maximizing value during development can be achieved through leveraging prior Knowledge and Platform Technologies to streamline Biologics Drug Product Development. In silico derived physicochemical properties can be compared to properties of previously developed assets to guide the prioritization of laboratory experimentation. This experimentation can be further streamlined though the use of High-Throughput Screening platforms.

In silico modeling platforms can also be employed towards development of fill/finish manufacturing processes. Advanced tools such as computational fluid dynamic modeling, in combination with prior knowledge, can be used to develop platform processes, which in turn reduces the large consumption of materials and development time associated with at-scale experimentation.

Furthermore, standardized Control Strategy platforms can further accelerate development.

Conclusions:

Implementation of standardized processes and platform technologies enable the acceleration and streamlining the development and commercialization of Biologic Drug Products

Biosketch

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Dr. Sébastien Gillet earned his PhD from the University of Namur, where he worked on the mechanisms of bacterial resistance to heavy metals.

He worked internationally as a post-graduate associate at Yale University for a couple of years in molecular biology research, contributing to a research project on bacterial chemotaxis.

Sébastien Gillet then supported different pharmaceutical companies as a consultant, leading innovation and automation projects related to bacterial processes.

Three years ago, he joined Catalent, where his background in molecular biology, bacterial research, and consulting allowed him to contribute to the development and transfer of a plasmid production platform.

Abstract

Sébastien Gillet

Standardized Platform Process With In-Line Cell Lysis Purifies Plasmid DNA Using A Single Chromatographic Step For Cell And Gene Therapy.

Plasmid DNA (pDNA) serves as a critical starting material for the production of advanced therapy medicinal products (ATMPs) in the field of cell and gene therapy. The growing demand for pDNA requires the development of manufacturing processes that can meet aggressive timelines while maintaining cost-effectiveness. Here we present a robust single-use process that enables seamless scale-up from research and development (R&D) to good manufacturing practice (GMP) grade, as well as the associated challenges.

This process involves bacterial cell growth in fermenters, alkaline cell lysis, and a streamlined chromatographic step. A key aspect of this approach is the implementation of a controlled cell lysis step, ensuring the production of high-quality pDNA that complies with regulatory agency standards. Notably, this process achieves efficient purification and polishing with just a single chromatographic step, simplifying the manufacturing process as well as reducing costs.

We will provide an overview of the platform process, what were the challenges and benefits of a standardized process and then share results on the quality attributes obtained through its implementation. Our findings demonstrate the effectiveness of this approach in generating pDNA that meets quality requirements set by regulatory agencies.

Biosketch

Marcel Hoefnagel, PhD

Senior Assessor Biopharmaceuticals
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- Trained as Biologist, with a PhD in Plant Biochemistry (Leiden University, 1993).
- Postdoc positions in Biochemistry, Biotechnology & modelling
- Assessor of Biopharmaceuticals (since 2002); Specialised in vaccines, allergens, biosimilars, immunogenicity, and Cell & Gene therapy products.
- Chair EMA Quality Innovation Group (QIG; since 2023). The QIG supports the translation of innovative approaches to the design, manufacture and quality control of medicines.
- Chair HMA Substance Validation Group (SVG; since 2020). The SVG is involved in development and maintenance of EU-SRS (EU- Substance Registration System); a database with all substances in medicinal products with their molecular structure.
- Involved in various academic research projects to support the assessment of (bio)pharmaceuticals and other regulatory activities.

Abstract

Marcel Hoefnagel

EMA QIG Listen & Learn Focus Group on Platform technologies; What have we learned?

Marcel Hoefnagel, Medicines Evaluation Board (CBG-MEB); Chair EMA QIG

The EMA Quality Innovation Group (QIG) organised a Listen & Learn Focus Group (LLFG) on Platform technologies in November 20241. In this open dialogue stakeholders were invited to share their thinking on platform technologies in pharmaceutical manufacturing and present case studies that use prior knowledge to support manufacturing platforms. The meeting aimed to also identify general scientific challenges with the use of platforms and possible solutions.
Three scenarios were discussed: 1) Platforms for medicinal products manufactured using prior knowledge, such as common manufacturing platform approaches (multiple MAs). 2) Platforms for medicinal products against agents which are or have a potential to cause serious cross-border threats to health e.g. pandemic/pandemic preparedness (one MA). 3) Platforms for the manufacture of personalised or individualised medicines ('one patient/group of patients-one product', one MA) e.g. covering different ultra-rare orphan indications.

Ten case studies were presented including: Platforms technologies for accelerating vaccine development, Ex vivo gene therapies for rare genetic diseases, mRNA-lipid nanoparticle and synthetic oligonucleotides. Topics discussed included: platform definition, minimum data required to show that a platform is established, applicability of a platform to different products and lifecycle management considerations. Although End-to-End approaches are feasible for some processes, some stakeholders proposed modular approaches. The possibility for CDMO to use data from different sponsors for efficient & accelerated development and process characterisation was discussed.

Biosketch

Veronika Jekerle

Veronika Jekerle, Ph.D. Head of Pharmaceutical Quality, Human Division, European Medicines Agency, Amsterdam, NL

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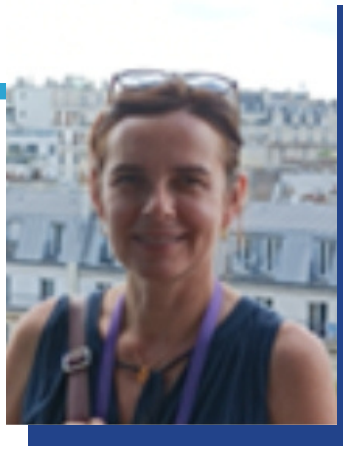
Veronika Jekerle obtained a pharmacy degree from University of Marburg, Germany (2001) and PhD in Molecular pharmacology, drug discovery from the University of Bonn, Germany and the University of Toronto, Canada.

Since March 2020, Veronika is heading the Pharmaceutical Quality Office for Human Medicines at EMA and responsible for scientific oversight and management of the pharmaceutical quality of human medicines throughout their life-cycle in the context of the benefit risk assessment. She is responsible for EMA's Quality domain working parties, which include the BWP, the QWP, the Biosimilar working party and the Quality Innovation Group.

She joined EMA in 2006 and held various positions as Product Team Lead for Biological medicinal product, Recombinant proteins, Vaccines, ATMPs and Biosimilar applications, Quality Specialist for Advanced Therapies, recombinant proteins including mABs, biosimilars and vaccines and Scientific Secretary to the Biologics Working Party (BWP) (2014-2020), leading regulatory science projects including prior knowledge, innovative manufacturing for Biologicals and flexibility in CMC requirements for PRIME (and other early access approaches) and more recently the revision of the variation classification guideline

Biosketch



Caroline Leveder, CL

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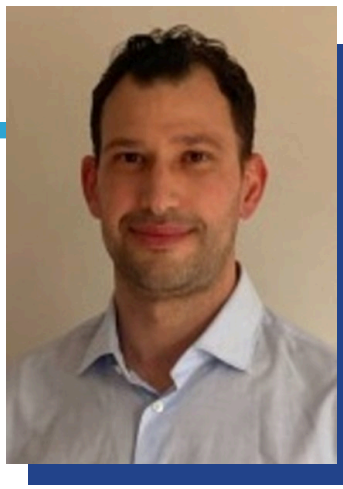
I've studied applied mathematics and statistics in France until the Master's degree except in Germany for the last year of the Bachelor's degree. I've joined Sanofi in 2006 after a job as Data Mining consultant for a marketing company and a Statistician role in R&D from Danone group.
In Sanofi, I have occupied 3 positions : 1st in R&D as Senior CMC-statistician, 2nd as "Statistical Tools and Methods" role in the Vaccines division/ Manufacturing Technology part and 3rd from 6 years asmanager of the CMC-Biologics Statistics group in the Data Sciences team from Global CMC Development.
In my current role, I lead the statisticians in charge of the support for the BLA/ CMC part at various sites (France, Germany, US, Belgium, India) and contributors to end-users tools development for our SMEs.

Biosketch



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Mourad Mellal is Director of Statistics at Catalent from end of March 2021. He received a Bachelor of Science degree in mathematics and computer science in 2008, a Master of Science degree in statistics in 2009 from Joseph Fourier University, Grenoble, France, and a Research Technological Diploma in applied and industrial mathematics in 2010 under a collaborative effort between Joseph Fourier University and Atomic Energy Commission. He worked at the French research center of cancers, Institute Curie, and He joined GSK vaccines in 2011 where He had increasing responsibilities. He started as a statistical consultant within industrialization department supporting statistics for processes and analytical methods development, validation and transfer. He moved to Quality Control department in 2013 managing statistics for quality operations and He became a leader of Quality Control and Global Industrial Operations Statistical team in 2016.

Biosketch

Shawn Novick

IABS Biotherapeutics Committee Chair

U.S.A.

E-mail: Novicksl@hotmail.com

Shawn Novick graduated from New York University and has been working in various positions in the Biotechnology industry for over 30 years, primarily focused on analytical development, characterization, and quality control. She has worked on several clinical and commercial products, including mAbs, ADCs, and other therapeutic proteins. Currently Shawn is a consultant with BioPhia Consulting and is Chair of the IABS Biotherapeutics Committee.

Biosketch

Nadine Ritter

President and Senior Analytics Advisor
Global Biotech Experts

- Dr. Nadine Ritter is an expert in the physiochemical and functional analytics utilized across the product lifecycle for biologically-derived products.
- She has a Ph.D. in cell and molecular biology from Rice University in Houston Texas. Prior to joining industry, Nadine was engaged in bone cell research for over 10 years at the University of Texas.
- After joining industry in 1992, Nadine has supported a wide variety of CMC studies for more than 200 IND/IMPDs and 70 BLA/MAAs for biologic therapeutic and vaccine products
- These include originator products of multiple modalities, biosimilar products, and gene and cell therapy products. She has also worked on several EUA products for ebola and covid.
- Nadine is an expert in analytical laboratory quality and compliance, providing guidance on lab quality system elements from R&D to GMP. Nadine has conducted numerous lab audits for due diligence or inspection readiness around the world.
- Nadine is an active member of several professional scientific organizations and serves on expert committees and organizing conferences and workshops.
- She is a frequent speaker and has numerous publications on technical, quality, and regulatory aspects of biological products.
- In 2022, Nadine was selected as the first woman to become a Distinguished Lifetime Fellow by CASSS, an international industry-regulatory organization.

Biosketch

Karen Rule

Director in Analytical Research & Development

Massachusetts, USA

Pfizer

Karen Rule is a Director in Analytical R&D (Biotherapeutics Pharmaceutical Sciences) at Pfizer, based in Massachusetts, USA.She has been with Pfizer for 24 years working in multidisciplinary areas including bioassay/potency development, analytical project lead and currently leads a group that is responsible for analytical regulatory strategy and authoring of analytical sections for the submissions across vaccines, mAbs, gene therapies, ADC and other mAb-like products. Her experience has covered method development, characterization, comparability, control strategy, method validation/transfer and health authority interactions. Over the past few years, Karen has been working with a team at Pfizer to help define the expectations and implement platform analytical procedures for late-stage products.

Abstract

Karen Rule

Commercial Submission Considerations for Platform Analytical Procedures

The updates to ICH Q2 and Q14 define analytical platform procedure and offer the opportunity to conduct abbreviated method validation through use of enhanced development, establishment of an analytical platform and risk assessment. Industry has extensive experience developing monoclonal antibodies (mAbs), including method development, validation, transfer, and implementation at commercial sites around the world for in-process, release, and stability testing. This prior knowledge, experience and historical data can be used to expand the application of platform analytical procedures to mAbs and mAb-like therapeutics intended to reduce redundant work by adopting a streamline abbreviated validation approach to enable rapid commercial readiness. This presentation will focus on providing examples of content and justifications needed in a commercial submission for a strategy establishing platform analytical procedures by leveraging prior knowledge (retrospective). Successful approaches and continued challenges will be highlighted.

Biosketch

Dr. Florian Semmelmann

Senior Scientist and Lab Head

Roche Diagnostics GmbH
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Dr. Florian Semmelmann is a scientist with a diverse background in biochemistry, biophysics, and bioinformatics. He studied biochemistry at the University of Regensburg in Germany and at the University of Colorado at Boulder in the USA. Dr. Semmelmann holds a Ph.D. in biochemistry and physical biochemistry.

Dr. Semmelmann works as a Senior Scientist and Lab Head at Roche Diagnostics GmbH in Penzberg, Germany. His work focuses on the development of analytical assays to quantify process-related impurities in biopharmaceuticals and advanced therapeutic modalities.

Abstract

Florian Semmelmann

Background:

Monitoring host cell proteins (HCPs) is critical in biopharmaceutical production due to their nature as heterogeneous process-related impurities and their classification as a Critical Quality Attribute (CQA) with potential safety implications. Effective HCP quantification ensures process consistency and product safety, making this a focal point for regulatory scrutiny from agencies like EMA and FDA.

Challenges:

The implementation of HCP monitoring using Enzyme-Linked Immunosorbent Assay (ELISA) methodology presents several challenges. These include securing the long-term supply, storage, and characterization of critical reagents necessary to support the ELISA platform for multiple products throughout their lifecycle. Additionally, the process demands large quantities of these reagents which necessitates meticulous reagent preparation and management. Rigorous characterization efforts are required to ensure ELISA suitability for new products, typically through mock run evaluations, adding to the complexity.

Proposed Approach:

Platform assays offer a standardized approach to HCP detection by utilizing a single antibody set and assay format across the pipeline, facilitating consistency and comparability. This strategy is feasible because HCP profiles tend to be similar across various products and cell lines, enabling the use of unified assays. The benefits include operational efficiency, streamlined regulatory approval processes, and the building of a comprehensive knowledge base.

Conclusions:

This presentation will provide insights into the importance of HCP monitoring, the methodologies employed, the advantages and feasibility of platform assays, and the challenges encountered. By addressing these scientific and regulatory aspects, the approach ensures the safety and efficacy of biopharmaceutical products throughout their development and lifecycle.

Biosketch

Marjorie Shapiro

Retired Regulator
USA

E-mail: shapirom@comcast.net

Dr. Marjorie Shapiro received her Ph.D. in immunology from the University of Pennsylvania where she studied molecular mechanisms underlying antibody diversity. She was at the FDA for over 30 years and is known for her expertise in therapeutic monoclonal antibodies and related products such as antibody-drug conjugates, bispecific antibodies, antibody cocktails, Fc-fusion proteins and biosimilar mAbs. She worked on several guidance documents while at the FDA, including several concerning the development of monoclonal antibodies, and the Platform Technology Designation Guidance document.

Abstract

Marjorie Shapiro

Thoughts from a former regulator on platform technologies, platform technology designation, and the use of contract manufacturing/testing organizations for biotechnology products.

The biotechnology industry has employed platform technologies for many years, but it took time for both industry and health authorities to get comfortable with the concept. One could argue that the FDA's 1997 Guidance Document "Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use" promoted the use of platform technology by introducing the concept of generic or modular virus clearance. However, it took several years for industry to adopt this approach as other health authorities were not yet ready to accept data from one product to support the development of a different, structurally related product.

Today many sponsors use prior knowledge and platform technologies to help speed up product development, but there may not always be a regulatory benefit. In addition, small companies that have only one product haven't yet developed a platform. These companies may rely on CDMOs that have developed a platform technology, but it is challenging to use data from other sponsors that use the same platform.

FDA guidance and regulations concerning platform technologies and Drug Master Files (DMF) will be presented. The presentation will include personal thoughts on the use of platform technologies and DMFs for biotechnology based on over 30 years of regulatory experience.

Abstract

Jason Starkey

Platforms in Biotechnology Development and Manufacturing: Laying the framework

Background
The application of platforms in biotechnology encompasses various processes, procedures, and technologies. However, the concept is greatly matured since its introduction, and there are many more real-world applications to illustrate the concept.

Challenges
The establishment and justification of these platforms may vary depending on their specific application or stage of development. The appearance and functionality of a platform will differ significantly based on its intended use or the entity responsible for its development.

Relevant Guidance
This presentation will focus on the utilization of platforms from an industry perspective, emphasizing the benefits and opportunities they provide. Key elements fundamental to platform use, including how they can streamline and enhance process and product understanding, will be addressed. Potential lifecycle considerations that aid in framing decisions for late-stage development and the internal management of platforms within companies will also be discussed. Additionally, the capability to transfer and sustain platforms across a global manufacturing network will be examined. Finally, as new modalities emerge and existing platforms are extended to meet evolving needs, considerations for future applicability will be explored.

Conclusions
As we advance in integrating platforms across various technologies, processes, and procedures, this approach has great potential to significantly enhance the pace of development and expedite the delivery of new medicines to patients.

Biosketch

Yinying Tao

Senior Director
46221 Indianapolis, (IN), USA
Bioproduct R&D / Eli Lilly and Company
1223 West Morris Street

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Yinying Tao is the Senior Director of Viral Safety and Purification Development at Eli Lilly and Company. Over her decade-long tenure, she has pioneered advancements in downstream development and led assets from early and late-stage development to market applications. Yinying led a team of scientists to establish adeno-associated virus (AAV) downstream capacity and spearheaded the AAV portfolio and technical innovations. She also serves as the CMC technical lead for projects across different modalities, including but not limited to monoclonal antibodies, bispecific antibodies, and bioconjugate assets.
Yinying holds a Ph.D. in Chemical Engineering from the University of Virginia. Before joining Lilly, she worked at Biogen as a senior downstream scientist. She has published 11 top-tier manuscripts and holds 2 patents in the downstream purification area.

Abstract

Yinying Tao

Leveraging Prior Knowledge for Process Parameter Classification in mAb Protein A Chromatography

Background:

Protein A (ProA) affinity chromatography is a widely used process in the pharmaceutical industry for purifying monoclonal antibodies and its analogous. The platform power of Protein A chromatography has fostered substantial knowledge and experience through mAb process development and commercialization over the past decades. While prior knowledge has been instrumental in streamlining design of experiments (DOE) study designs, an innovative step remains unexplored, i.e., the complete elimination of product-specific small-scale studies by solely leveraging prior knowledge for process parameter classification.

Materials & Methods:

We have leveraged prior knowledge from prior ten molecules for process parameter classification of the ProA unit operation, eliminating product-specific small-scale studies in developing manufacturing control strategies for monoclonal antibodies and derivatives. Statistical analysis using a Bayesian hierarchical model was used to predict a pooled (platform) estimate for each process parameter effect based on the experimental data from historical studies.

Results/Conclusions:

By leveraging this historical data package, we directly supported the classification of ProA process parameters for new therapeutic antibodies, effectively replacing the need for product-specific process characterization evaluations. This approach has been positively received by global regulatory agencies during the market authorization filings for two Lilly's products.

Biosketch

Yannick Van Haelst

Nonclinical Biostatistician, CMC Biologics BE9052, Zwijnaarde, Belgium Sanofi SA 21, Technologiepark-Zwijnaarde

E-mail: yannick.vanhaelst@sanofi.com

Yannick Van Haelst graduated as Biochemist with post-master's degree in informatics at Ghent University. He has been working in application support for life science analytics and in academic research before joining the pharmaceutical industry. He has 17 years of experience in the industry, of which 11 as site statistician at Novartis, progressing with the site from synthetics to biologics. In 2019, he moved to a senior lead statistician position in global CMC development at Sanofi where he now supports across different pharmaceutical modalities with a key focus on biologics.

Abstract

Yannick Van Haelst

Capturing the Essence of a purification step: Data-Driven simplification of a Protein Purification platform.

Early-stage development of a protein platform traditionally involved extensive Response Surface Model (RSM) DOEs for downstream purification process optimization. However, in early stages, speed is crucial to reduce overall product development timelines. To streamline one critical purification chromatography step ,and to achieve the final product quality, we conducted a meta-analysis of historical DOEs, employing a two-stage approach combining Bayesian screening and effect size filtering.

Biosketch

Marc Verhagen

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Marc Verhagen, Ph.D. is the Head of Bioanalytics Mammalian US within the CMC Biologics Development organization at Sanofi, where he oversees analytical development activities to support Sanofi's pipeline. Before joining Sanofi, Dr. Verhagen served as the Executive Director of Analytical Development at Allergan, Inc., where he advanced various early- and late-stage biologics development programs and supported commercial products. He also held the position of Associate Research Scientist in the Department of Biochemistry and Molecular Biology at the University of Georgia. Dr. Verhagen earned his B.Sc. and Ph.D. in Biochemistry from the Agricultural University in Wageningen, the Netherlands.

POSTERS

Poster

Nikolette McCombs

Accelerating Biologics Development with Platform Solutions

Authors: Nikolette L. McCombs, Shaunak Uplekar, Derek Ryan, Leslie Wolfe, David Brown, Sigma Mostafa

Accelerating Biologics Development with Platform Solutions

Nikolette L. McCombs[1]*, Shaunak Uplekar[2], Derek Ryan[1], Leslie Wolfe[2], David Brown[2], Sigma Mostafa[3]

KBI BIOPHARMA

Abstract Number xxxxx

1. Introduction

The integration of platform technologies has become essential in streamlining biologics development, enabling rapid progression from early-stage research to first-in-human (FIH) trials. KBI Biopharma's SUREtechnology Platform™, powered by Selexis®, exemplifies how platforming principles can enhance efficiency, consistency, and regulatory readiness in cell line development and biomanufacturing. Here we will highlight the role of the SUREtechnology Platform™ in optimizing cell line development by generating stable, high-performing cell lines tailored for biologics production. We will discuss how leveraging streamlined workflows, and prior knowledge significantly reduces bottlenecks in cell line selection and enables a seamless transition from development to preclinical toxicology studies. Additionally, we will explore how platform-based approaches align with regulatory expectations by providing a structured framework for justification, risk assessment, and dossier support. We will illustrate how these strategies accelerate pathways to first-in-human trials, with a particular focus on analytical strategies that support high-throughput automation and streamlined workflows to expedite method development and process development analytics. These approaches enable CDMOs and their partners to bring innovative medicines to the clinic faster while optimizing development timelines and strengthening regulatory interactions from Phase 1 through commercialization.

2. Technology Levers to Drive Speed

Cell Line Technology
Analytical Testing Automation
Electronic Solutions
Development Facility Design
Upstream Process Automation
Process Analytical Technologies
Platform Scalability

- Integrated technology platforms accelerate development speed and enhance product quality.
- Automation, data-driven solutions, and scalable platforms enable seamless progression from discovery to manufacturing.

3. SUREmAb™: Where Platform Meets Acceleration

Optimized | Streamlined | Platform process | Robust | Scalable

- **New transposase-based offering** accelerates timelines with consistent performance across scales, supporting efficient and robust development.
- **Transfection to IND-enabling tox material in 5 months** using top-performing clone pools—or 6 months with a final clone, minimizing delays.
- **Client-centric, platform-driven approach** balances speed, quality, and flexibility—tailored for your molecule format, budget, and material needs.

DNA Synthesis
Enriched Pool Generation
RCB Generation
Cell Line Stability Evaluation
Upstream Process Development
Downstream Process Development
IND Enabling Tox Material Generation
Transfection
Shipment to customer
Months 01 02 03 04 05 06 07

4. High-throughput Capabilities and Automation Platforms

TECAN® EVO ELISA
Fully integrated in PD support and MD/ME workflows

TECAN® Fluent Capture
Robocolumn® est. platform for late phase programs

StreamLink® CC-15
Fully automated membrane small scale capture

Waters™ Andrew+
N-Glycan preparation
CGE sample preparation
HPLC sample preparation

SciEx Biophase 8800
Eightfold throughput for CGE

LIMS/Digital Solutions
ELN batch summaries
Empower custom field reports
Visualizations of data status

5. PROGRAMview™ as a New Standard of Data Visualization

PROGRAMVIEW™

Supporting Applications

- **Unified Access Point:** PROGRAMview™ centralizes data, documents, and team discussions—eliminating silos and reducing reliance on emails and slide decks.
- **Accelerated Timelines:** Real-time access to comprehensive project data enables faster decisions and reduces delays across development workflows.
- **Streamlined Collaboration:** Built-in tools for commenting, document sharing, and @mentioning make cross-functional teamwork seamless and transparent.
- **Future-Ready Platform:** Designed with scalability and agile improvement in mind, PROGRAMview™ evolves with your program needs.

6. Conclusion

Parallel Approach Only: i.e., SUREmAb™ Process Development Phase
Upstream Clone Selection and Platform Process Implementation
Downstream Platform Process Implementation
Analytical / Formulation Activities

SUREmAb™ Process Development Including Automation and Analytical Data digitalization
Upstream Clone Selection and Platform Process Implementation
Downstream Platform Process Implementation
Analytical / Formulation Activities
-25%

- Integrating Automation and Analytics data Digitalization into a SUREmAb™ program
- Enabled reduced process and analytics development timelines while maintaining key milestones and process targets
- Platform workflows for SURE CHO-M® Cell Lines
- **Accelerating FIH timelines without compromising robustness**

KBI's vertically integrated solutions, spanning from CLD to cGMP, are designed for speed, consistency, and scalability across diverse biologic programs. The new transposase-based offering significantly reduces timelines while enhancing reproducibility. Embedded digital tools streamline data processing and collaboration with clients, and a strong focus on automation enables efficient execution of multiple programs in parallel. With this platform, transfection to IND-enabling tox material is achievable in just 5 months using a pool of top clones, or 6 months with a final clone.

1. Analytical Development, KBI Biopharma, Durham NC, United States
2. Process Development, KBI Biopharma, Durham NC, United States
3. KBI Biopharma, United States

KBI Biopharma | 1101 Hamlin Rd, Durham, NC 27704 kbibiopharma.com A JSR Life Sciences Company

Poster

Nuria Gomez

Accelerating CAR-T Manufacturing: Establishing an Automation-Driven Analytical Development Platform

Authors: Lander Robays, Mourad Mellal, Angela Castela, Nuria Gomez Santos

Background & Aim
The production of CAR-T and TCR-T therapies often rely on manual, time-intensive analytical processes, delaying the delivery of critical treatments to oncology patients. To overcome these challenges, an automation-driven analytical platform has been developed to accelerate batch release timelines, enable faster vein-to-vein delivery, and ensure fresh, high-quality products for clinical use. This study applies an statistical method for the analysis of datasets generated from different cell therapy analytical technologies for flow cytometry, supported by cytokine release assays and cytotoxicity measurements.

Methods
Automated analytical testing for CAR-T was implemented using cartridge-based flow cytometry, cartridge-based cytokine detection and impedance-based real-time cell analysis. Bland-Altman method was used for comparability studies.

Results
Comparability studies of automated versus conventional flow cytometry confirmed consistent outcomes in processing patients' starting materials. The integration of specific CAR-T cell identifying antibodies into cartridge-based flow cytometry further enhanced the technology's capability for in-process control strategies and linked it to final product characterization for CAR transduction. We then introduced cartridge-based cytokine detection technology to the platform by comparing key cytokines, like IFN-γ, with traditional ELISA. A real-time killing assay was developed to assess cytotoxicity (up to 85% of killing) in real-time for in-process and product samples, significantly reducing the time required for analytical testing and minimizing hands-on time.

Conclusion
To address the need for accelerated analytical data generation for CAR-T cell therapy manufacturing, a cartridge-based flow cytometry and automated cytokine detection methods for in-process control and final product analysis were implemented. Furthermore, real-time cell analysis utilizing impedance-based cytotoxicity assays provides immediate insights into the cytolytic responses of CAR-T cells and other immunotherapeutic products towards tumor cells.

Poster

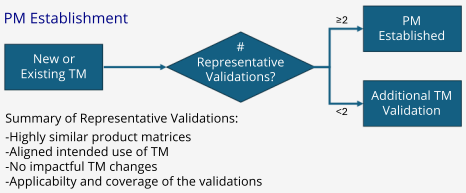
Karolien Sermon

Platform Test Method Validation

Platform Test Method (PM) Validation

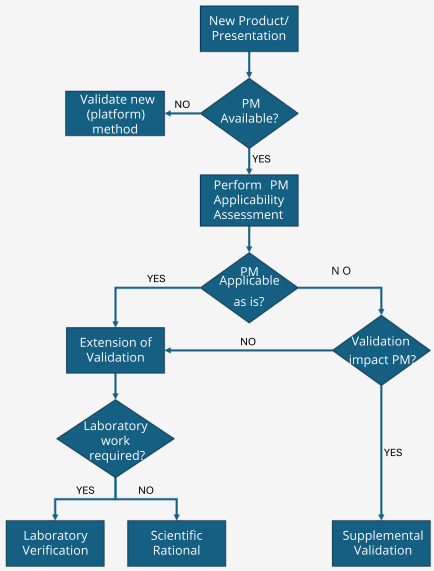
Process flow

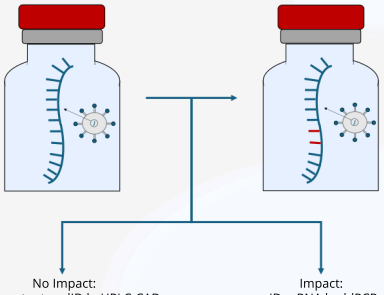
PM Establishment



Summary of Representative Validations:
-Highly similar product matrices
-Aligned intended use of TM
-No impactful TM changes
-Applicabilty and coverage of the validations

New Product/Presentation PM Implementation





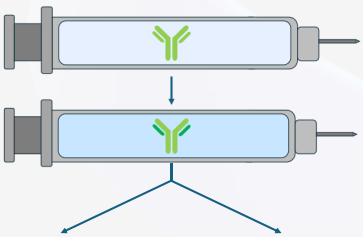
No Impact:
-Lipidcontent andID byHPLC-CAD
-RNA encapsulationandcontent by Ribogreen fluorescence

Impact:
-ID mRNA byddPCR

-Non-platform methods(e.g. PotencybyIVE)

Advantages

Case 2: mAbs



No Impact:
-Protein Concentration by SoloVPE
-%HMMS/%monomer by SE-HPLC

Impact:
-ID byPeptide mapping

-Non-platform methods(e.g. PotencybyELISA/ cell basedassay)

Challenges

-Initial investment to Establish Platform Method

-PM Applicability Assessment = Critical Step

-Complex Management of PM across Multiple QC Labs

Pfizer Breakthroughs that change patients' lives

Poster

Amada Savadogo

Accelerating FIH Timelines Through Platform Analytical Methods

Authors: Adama Savadogo, Hajer Souaifi-Amara

Accelerating CMC timelines for First In Human (FIH) studies represents a challenge for CMC teams including the Analytical Development teams. Traditionally, method development and qualification are time-consuming activities that need to be completed to allow release of clinical supplies and ensure that method information can be summarized in the IND/IMPD.

To decrease the time to complete these activities, and reduce the associated workload, Sanofi has developed platform methods for both physicochemical and residual impurity methods. The platform methods were established through a global co-qualification approach performed across three Sanofi R&D sites. Selected highlights & statistical methodology from this initiative are presented to demonstrate the potential of this approach.